K113318 1/2

JAN 12 2012

5. 510(k) Summary

Device Trade Name:	ACUTE Innovations Modular RibLoc Fixation System
Manufacturer:	ACUTE Innovations, LLC 21421 NW Jacobson Road, Suite 700 Hillsboro OR, 20005
Contact:	Ms. Mariah Knight Regulatory & Quality Manager 503.686.7200
Date Prepared:	November 9, 2011
Classifications:	21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories and 21 CFR 888.3040, Smooth or threaded metallic bone fixation fasteners
Class:	II
Product Codes:	HRS and HWC

Indications for Use:
The ACUTE Innovations® Modular RibLoc System is intended to stabilize and provide fixation for fractures, fusions, and osteotomies of the ribs, and for reconstructions of the chest wall and sternum.

Device Description:
The ACUTE Innovations® Modular RibLoc System consists of plates and screws for fractures, fusions, and osteotomies. The plates are pre-contoured to minimize bending which is done intraoperatively. Instrumentation is supplied with the implants to aid in the insertion of the plates and screws. All plates and screws are manufactured from titanium or titanium alloy.

Predicate Devices:
Comparative information presented in the 510(k) supports the substantial equivalence of the ACUTE Innovations® Modular RibLoc System to the following predicate devices: MedXpert STRATOS (K073556); ACUTE Innovations® RibLoc System (K051410); and ACUTE Innovations Sternal Fixation System (K101170).

Substantial Equivalence:
The components of the Acute Innovations® Modular RibLoc System are substantially equivalent to the identified predicates with respect to its indications for use, geometry, available sizes, materials, methods of fixation to bone, and performance.

Preclinical Testing:
The non-clinical tests performed by the company include an analysis of strength of the ACUTE Innovations® Modular RibLoc plates. The results of the performed tests demonstrate that the ACUTE Innovations® Modular RibLoc System is substantially equivalent to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JAN 12 2012

ACUTE Innovations, LLC
% Ms. Mariah Knight
21421 NW Jacobson Road, Suite 700
Hillsboro, OR 97124

Re: K113318
Trade/Device Name: ACUTE Innovations Modular RibLoc Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: November 9, 2011
Received: November 10, 2011

Dear Ms. Knight:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K113318

Device Name: ACUTE Innovations® Modular RibLoc System

The ACUTE Innovations® Modular RibLoc System is intended to stabilize and provide fixation for fractures, fusions, and osteotomies of the ribs, and for reconstructions of the chest wall and sternum.

Prescription Use ___√___ (Part 29 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (29 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth Mahoney

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K113318